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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/038,894	03/11/1998	ROLAND STOUGHTON	24730-2202	8909

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EXAMINER	
MELLER, MICHAEL V	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/038,894	STOUGHTON ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18,32-36,38,41 and 42* is/are pending in the application.

4a) Of the above claim(s) *17,33,38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-16, 18, 32, 34-36, 41, 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The rejections of record are vacated and the following office action is hereby presented pursuant to the Board of Appeal's decision filed 5/18/2006.

Election/Restrictions

The election of species of record is maintained for the reasons of record. Applicant elected trauma as the disease/condition, futhan (nafamostate mesilate) as the activation lowering therapy and free radical production as the cell activation assessment method.

Thus, claims 17, 33, 38 are withdrawn from further consideration as being drawn to non-elected subject matter. This requirement was already made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 10, 12, 13, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al.

As the Board of Appeals noted in their decision of May 18, 2006, claim 32 reads on bed rest. The Board stated that the claim reads on a subject recognizing that the subject is experiencing inflammation. The Board stated also that it would seem to them quite clear that inflammation results from the release of inflammatory mediators. Therefore, administering an anti-inflammatory to the subject would prevent a disease or disorder that is within the scope of applicant's claimed invention. The Board stated that according to Adams (column 1, lines 1-20), "[a]n early event in the response of most inflammatory cells to immunologic activation and other stimuli is the release of newly formed products (mediators) which alter the function and biochemistry of surrounding

cells and tissues." Therefore, all subjects experiencing inflammation will have elevated levels of inflammatory mediators. Adams proposes to treat this condition by administering a compound of Formula (I). See abstract, and column 4, line 50-column 5, line 17. Note that the claims are met since assessment was done and activation levels were increased (since inflammation was experienced) and that activation lowering therapy was administered before treatment for the disease since the protease inhibitor is the treatment.

It is noted that the Board very clearly delineated that in the appellant's specification or claims that there is no requirement that a blood test or other "procedure" be used to assess cell activation. Accordingly (the Board concluded in their decision) that the claims reads on a subject recognizing that the subject is experiencing inflammation, see pages 10-11 of the Board's decision.

A close examination of Adams reveals that Adams is treating inflammation. The Board considered Adams to be on point with the claimed invention, thus Adams is applied herein for the reasons cited by the Board.

Adams is treating trauma since as noted by Groutas, inflammation is associated with tissue trauma, see Groutas, column 1, lines 10-20.

Claims 10, 12-16, 32, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Groutas.

Groutas teaches that inflammation is associated with tissue trauma. Groutas also teaches that alpha-1-proteinase inhibitor is administered to reduce inflammation (see

column 1, lines 1-45). Thus, as with the teachings of Adams as noted by the Board, the administration of alpha-1-proteinase will also treat the inflammation within the scope of the claims.

It is noted that the Board very clearly delineated that in the appellant's specification or claims that there is no requirement that a blood test or other "procedure" be used to assess cell activation. Accordingly (the Board concluded in their decision) that the claims reads on a subject recognizing that the subject is experiencing inflammation, see pages 10-11 of the board's decision.

Claims 10, 11, 32 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Rabkin et al.

Rabkin teaches that free radical production is measured using assays such as colormetric assays. Thus, when administering such compounds of Rabkin one can assess the damage of a disease/condition by assessing the free radical production as taught by Radkin (column 9, lines 40-50). Note also that Rabkin teaches that his invention could be administered to someone who has inflammatory disorders, see column 2, lines 40-60.

It is noted that the Board very clearly delineated that in the appellant's specification or claims that there is no requirement that a blood test or other "procedure" be used to assess cell activation. Accordingly (the Board concluded in their decision)

that the claims reads on a subject recognizing that the subject is experiencing inflammation, see pages 10-11 of the board's decision.

Claims 10, 11, 32 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/15707.

WO teaches that free radical production is assayed by using immunoassay methods, see abstract, page 20, line 15-page 21, line 10. WO uses its compositions to prevent inflammatory diseases, see abstract.

WO states that not only may this permit appropriate actions to avoid the pathogenic potential of these antibodies, but the detection serves in itself as a sensitive measure of ongoing oxidative damage. Thus, the detection of such antibodies may be used as the basis for modifying or terminating certain therapies or avoiding certain exposure risks (page 20, line 15- page 21, line 10).

It is noted that the Board very clearly delineated that in the appellant's specification or claims that there is no requirement that a blood test or other "procedure" be used to assess cell activation. Accordingly (the Board concluded in their decision) that the claims reads on a subject recognizing that the subject is experiencing inflammation, see pages 10-11 of the board's decision.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10, 12-16, 18, 32, 34-36, 41 are rejected under 35 U.S.C. 103 as being obvious over Groutas in view of JP 409040579.

Groutas teaches that inflammation is associated with tissue trauma. Groutas also teaches that alpha-1-proteinase inhibitor is administered to reduce inflammation, see coulumn 1, lines 1-45. Thus, as with the teachings of Adams as noted by the Board, the administration of alpha-1-proteinase will also treat the inflammation within the scope of the claims.

Groutas does not teach that futhan (nafamostat mesilate) is used as the specific protease inhibitor.

JP teaches that nafamostat mesilate is well known to be used to treat inflammation, specifically inflammatory bowel disease, see abstract. It establishes that one of ordinary skill in the art would have known at the time the invention was made that nafamostat mesilate (futhan) was known to treat inflammation.

Since JP clearly establishes that futhan was known at the time the invention was made to treat inflammation and since Groutas establishes that serine proteinase inhibitors such as alpha-1-proteinase inhibitor were known to treat inflammation then it would have been obvious to use futhan instead of alpha-1-proteinase since they both were known to treat inflammation at the time the invention was made and it clearly would have been within the purview of one of ordinary skill in the art to use either alpha-1-proteinase or futhan to treat inflammation. It is clear from JP '579 that the medicine (the fibrin paste containing the nafamostat mesilate-futhan) was capable of manifesting excellent effects on the suppression of relapse and keloplasty in the postoperative anastomosed part of the inflammatory bowel disease thus motivating one of ordinary skill in the art to use the nafamostate mesilate instead of using of the alpha 1 proteinase since nafamostate mesilate was clearly known to achieve the above excellent effects.

It is noted that the Board very clearly delineated that in the appellant's specification or claims that there is no requirement that a blood test or other "procedure" be used to assess cell activation. Accordingly (the Board concluded in their decision) that the claims reads on a subject recognizing that the subject is experiencing inflammation, see pages 10-11 of the board's decision.

Thus, to use futhan (nafamostate mesilate) instead of alpha-1-proteinase as the protease inhibitor would have been *prima facie* obvious to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller
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Art Unit 1655

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